

## REMARKS

The Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **I. Status of the claims**

Claims 8-10, 21-22, 24-25, 33, 35, 37-43, and 56-141 were previously canceled without disclaimer or prejudice thereof.

Claims 5, 12, 13 are requested to be canceled without disclaimer or prejudice thereof.

Claims 1, 2, 11, 14-20, 23, 26-32, 34, 36 and 44-55 are withdrawn.

Claims 3 and 4 are currently being amended to recite elected subject matter. Claim 3 recites “[a]n isolated polynucleotide encoding a polypeptide, wherein the polypeptide consists of the amino acid sequence of SEQ ID NO: 13.” Claim 4 recites “[t]he isolated polynucleotide of claim 3 wherein the polynucleotide sequence consists of SEQ ID NO: 56.” The amendments add no new matter and exemplary support is found throughout the specification, for example at claim 1 and claim 12. Entry and examination of the claims as amended is respectfully requested.

Claims 6 and 7 are currently being amended to recite the article “the” instead of “a” as suggested in the Office Action at page 5. The amendments add no new matter and entry and examination of the claims as amended is respectfully requested.

Withdrawn method claims 14, 16, 28 and 29 are also amended to depend from independent claim 3 instead of canceled claim 12. The amendments add no new matter and entry thereof is respectfully requested.

Claims 142, 143 and 144 are being added and relate to polynucleotide sequence complements and RNA equivalents of the polynucleotide sequences of claims 3 and 4. The new claims add no new matter and exemplary support can be found throughout the specification, for example at claim 12. Entry and examination of new claims 142-144 is respectfully requested.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-4, 6-7, 11, 14-20, 23, 26-32, 34, 36, 44-55, and 142-144 are now pending in this application, with claims 3, 4, 6, 7 and 142-144 under examination.

## **II. Oath**

The Office Action asserts that “[t]he Oath of April 27, 2007 is objected to because it is not signed by all inventors.” (Office Action at page 2). The Applicants respectfully bring to the Examiner’s attention the Decision on Renewed Petition under 37 C.F.R. § 1.47(a) and Petition under 37 C.F.R. § 1.182, dated May 10, 2007. In the Decision, the Office *granted* Applicants’ petition under 37 C.F.R. § 1.47(a), filing when an inventor(s) refuses to sign. Pursuant to the Decision, inventors Soo Yeun Lee, Ameena R. Gandhi, Amy D. Wilson and Joseph P. Marquis are included in this application, although they refused to sign a declaration.

Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

## **III. Claim objections**

Claims 3-7, 12 and 13 are objected to for being dependent from non-elected claims and for reciting non-elected subject matter.

Claims 5, 12 and 13 are canceled, thereby obviating the objection with respect to these claims. Claims 3 and 4 are amended to be independent claims and to omit reference to non-elected subject matter.

Accordingly, reconsideration and withdrawal of the objections is respectfully requested.

#### **IV. Claim rejection – 35 U.S.C. § 101**

Claims 3-7, 12 and 13 are rejected under 35 U.S.C. § 101 as allegedly failing to meet the utility requirement. Specifically, the Office Action asserts that although the specification provides data regarding homology of the claimed sequences to known signature sequences, protein domains, and other polypeptides, such homology data is not an assertion of utility. (Office Action at page 3). The Office Action continues, asserting that one of ordinary skill in the art would not reasonably believe that a single protein would have all the activities of the identified signature sequences and homology regions (*e.g.*, serine protein kinase activity, receptor tyrosine kinase activity, G-protein coupled receptor activity, etc.) (Id.) The Office Action further asserts that certain of the utilities provided in the specification (*e.g.*, therapeutics, diagnostics, antibody production and identification of modulators) are general and would apply to every member of a general class of materials and that such utilities are not specific to the claimed sequences. (Id.) The Applicants respectfully traverse this ground for rejection.

##### **A. Utility requirement**

The specification must only include an assertion of utility “for any practical purpose (*i.e.*, it has a specific and substantial utility)” which would be considered credible by one skilled in the art. (*See e.g.*, M.P.E.P. § 2107.II). With respect to a credible assertion, the M.P.E.P. states as follows:

Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide ***one credible assertion of specific and substantial utility*** for each claimed invention to satisfy the utility requirement. [M.P.E.P. § 2107.II, emphasis added.]

Moreover, case law clearly teaches that the utility requirement is met if the claimed invention is capable of achieving any useful result or serving any beneficial end. (See *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689 (1966) (citations omitted, emphasis added)).

**B. The claimed invention has a specific, substantial and credible utility**

The Applicants respectfully assert that the claimed polynucleotides and encoded polypeptide have a specific, substantial and credible utility. While being useful for therapeutics, diagnostics, antibody production and identification of modulators, the claimed sequences are also useful as markers for brain tissue. As described in the specification, tissue specific expression was determined by microarray analysis, and “[t]he expression of SEQ ID NO: 56 was increased by at least two-fold in brain as compared to the reference sample.” (Specification at page 102, lines 3-4 and 17-18). The specification states that “[t]issue contributing to the reference sample...[included] brain...heart...kidney...lung...placenta...small intestine...spleen...stomach...testis...and uterus.” (Specification at page 102, lines 5-8). Thus, SEQ ID NO: 56 has a specific, substantial and credible utility as a marker for brain tissue.

It is asserted that new claims 142-144 meet the utility requirement and are patentable.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

**V. Claim rejection – 35 U.S.C. § 112, second paragraph**

Claims 3-7, 12 and 13 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 5, 12 and 13 have been canceled, thereby obviating the rejection with respect to these claims.

Claim 3 is rejected because the phrases “naturally occurring” and “a polypeptide of claim 1” allegedly render the claim vague. (Office Action at page 4). Claim 3 has been amended to omit both phrases.

Claims 4, 6 and 7 are rejected as vague for use of the article “a” instead of “the.” (Office Action at page 5). Claims 4, 6 and 7 have been amended as recommended by the Office Action to replace “a” with “the.”

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

**VI. Claim rejection - 35 U.S.C. § 112, first paragraph, enablement**

**A. Enablement – alleged lack of utility**

Claims 3-7, 12 and 13 are rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. Specifically, the Office Action asserts that “since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility...one skilled in the art clearly would not know how to use the claimed invention.” (Office Action at page 4). The Applicants respectfully traverse this ground for rejection.

As noted above in section IV, the claimed invention has a specific, substantial and credible utility. It is also asserted that new claims 142-144 meet the enablement requirement and are patentable.

As such, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

**B. Enablement**

Claims 3, 6, 7 and 13 are rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. Specifically, the Office Action asserts that the specification does not provide enablement for any polynucleotide encoding a polypeptide with 90% identity to SEQ ID NO: 13 or any fragment of SEQ ID NO: 56 of at least 60 contiguous nucleotides. (Office Action at pages 5-6). The Applicants respectfully traverse this ground for rejection.

Claim 13 has been canceled thereby obviating the rejection with respect to this claim.

Without conceding to the correctness of the Office Action assertions, claims 3, 6 and 7 have been amended to omit reference to “90% identity” and to any fragments of SEQ ID NO: 56.

Claim 3 now recites “An isolated polynucleotide encoding a polypeptide, wherein the polypeptide **consists** of the amino acid sequence of SEQ ID NO: 13.” This claim is fully enabled by the specification, *see e.g.*, SEQ ID NO: 13. And, given that the genetic code is well known in the art, one of ordinary skill would be able to easily make and use the claimed polynucleotides as recited in the claim. Likewise, claims 6 and 7, which depend from claim 3, are also enabled (*see e.g.*, specification at page 52, lines 1-5; page 53, lines 9-35, continuing through page 57 line 19, describing cloning and expression of KPP).

It is submitted that new claims 142-144 are also fully enabled and are patentable.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

**VII. Claim rejection – 35 U.S.C. § 102(b)**

Claims 3-7, 12 and 13 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by PCT/US00/34263 (WO 01/53312, hereinafter “Tang *et al.*”). Specifically, the Office Action asserts that “Tang teaches a polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO: 56, wherein the polypeptide encoded by Tang’s polynucleotide has 94% homology with SEQ ID NO: 13 herein.” (Office Action at page 8). The Office Action continues, asserting that “Tang et al further teaches vectors that comprise their polynucleotides and fragments of their polypeptides.” The Office Action concludes, therefore, that Tang *et al.* anticipates claims 3-7, 12 and 13. The Applicants respectfully traverse the rejection.

Claims 5, 12 and 13 are canceled, thereby obviating the rejection with respect to these claims.

As noted above in section VI.B., claims have been amended to omit reference to fragments of SEQ ID NO: 56 and polynucleotides comprising at least 60 contiguous nucleotides of SEQ ID NO: 56. Accordingly, this reason for rejection is obviated.

The sequence alignment below is between SEQ ID NO: 13 (“query”) and GenBank reference AL022329 (“sbjct”) which is the Accession Number of SEQ ID NO: 596 (see Table 2 at page 158 of Tang *et al.*). The amino acid sequence was available on GenBank under the same Accession Number AL022329. Difference between the amino acid sequences are highlighted.

**Alignment of SEQ ID NO: 13 and AL022329 (WO 01/53312)**

Query	1	MADLEAVLADVSYLMAMEKSKATPAARASKRIVLPEPSIRSVMQKYLAERNEITL	60
		MADLEAVLADVSYLMAMEKSKATPAARASKRIVLPEPSIRSVMQKYLAERNEIT	DKIFN
Sbjct	1	MADLEAVLADVSYLMAMEKSKATPAARASKRIVLPEPSIRSVMQKYLAERNEIT	FDKIFN
Query	61	QKIGFLLFKDFCLNEINEAVPQVKFYEEIKEYEKLDNEEDRLCRSRQIYDAYIMKELLSC	120
		QKIGFLLFKDFCLNEINEAVPQVKFYEEIKEYEKLDNEEDRLCRSRQIYDAYIMKELLSC	
Sbjct	61	QKIGFLLFKDFCLNEINEAVPQVKFYEEIKEYEKLDNEEDRLCRSRQIYDAYIMKELLSC	120
Query	121	SHPFSKQAVEHVQSHLSKKQVTSTLFPYIEEICESLRGDIQKFMESDKFTRFCQWKNV	180
		SHPFSKQAVEHVQSHLSKKQVTSTLFPYIEEICESLRGDIQKFMESDKFTRFCQWKNV	
Sbjct	121	SHPFSKQAVEHVQSHLSKKQVTSTLFPYIEEICESLRGDIQKFMESDKFTRFCQWKNV	180
Query	181	ELNIHMTMNEFSVHRIIGRGGFGEVYGCRKADTGKMYAMKCLDKKRIKMKQGETLALNER	240
		ELNIHMTMNEFSVHRIIGRGGFGEVYGCRKADTGKMYAMKCLDKKRIKMKQGETLALNER	
Sbjct	181	ELNIHMTMNEFSVHRIIGRGGFGEVYGCRKADTGKMYAMKCLDKKRIKMKQGETLALNER	240
Query	241	IMLSLVSTGDCPFIVCMTYAFHTPDKLCLFILDLMNGGDLHYHLSQHGVFSEKEMRFYATE	300
		IMLSLVSTGDCPFIVCMTYAFHTPDKLCLFILDLMNGGDLHYHLSQHGVFSEKEMRFYATE	
Sbjct	241	IMLSLVSTGDCPFIVCMTYAFHTPDKLCLFILDLMNGGDLHYHLSQHGVFSEKEMRFYATE	300
Query	301	IILGLEHMHNRFFVYRDLKPANILLDEHGHARISDLGLACDFSKKKPHASVGTHGYMAPE	360
		IILGLEHMHNRFFVYRDLKPANILLDEHGHARISDLGLACDFSKKKPHASVGTHGYMAPE	
Sbjct	301	IILGLEHMHNRFFVYRDLKPANILLDEHGHARISDLGLACDFSKKKPHASVGTHGYMAPE	360
Query	361	VLQKGTAYDSSADWFSLGCMFLKLLRGHSPFRQHKTCDKHEIDRMTLTVNVELPDTFSPE	420
		VLQKGTAYDSSADWFSLGCMFLKLLRGHSPFRQHKTCDKHEIDRMTLTVNVELPDTFSPE	
Sbjct	361	VLQKGTAYDSSADWFSLGCMFLKLLRGHSPFRQHKTCDKHEIDRMTLTVNVELPDTFSPE	420
Query	421	LKSLLEGLLQRDVSKRLGCHGGGSQEVKEHSFFKGVDWQHVVYLQKYPPLIPPRGEVNAA	480
		LKSLLEGLLQRDVSKRLGCHGGGSQEVKEHSFFKGVDWQHVVYLQKYPPLIPPRGEVNAA	
Sbjct	421	LKSLLEGLLQRDVSKRLGCHGGGSQEVKEHSFFKGVDWQHVVYLQKYPPLIPPRGEVNAA	480
Query	481	DAFDIGSFDEEDTKGIKLLDCDQELYKNFPLVISERWQQEVTETVYEAVNADTDKIEARK	540
		DAFDIGSFDEEDTKGIKLLDCDQELYKNFPLVISERWQQEVTETVYEAVNADTDKIEARK	
Sbjct	481	DAFDIGSFDEEDTKGIKLLDCDQELYKNFPLVISERWQQEVTETVYEAVNADTDKIEARK	540
Query	541	RAKNKQLGHEEDYALGKDCIMHGYMLKLGNPFLTQWQRRYFYLFNRLWRGEGESR---	597
		RAKNKQLGHEEDYALGKDCIMHGYMLKLGNPFLTQWQRRYFYLFNRLWRGEGESR	
Sbjct	541	RAKNKQLGHEEDYALGKDCIMHGYMLKLGNPFLTQWQRRYFYLFNRLWRGEGESRQNL	600
Query	598	-----SDPEFVQWKKEINETFKEAR	622
		SDPEFVQWKKEINETFKEA+RLLLR	
Sbjct	601	LTMEQILSVEETQIKDKKCILFRIKGGKQFVLQCESDPEFVQWKKEINETFKEAQ	660
Query	623	APKFLNKPRSGTVLPPKPSLCHRNSNGL	650
		APKFLNKPRSGTVLPPKPSLCHRNSNGL	
Sbjct	661	APKFLNKPRSGTVLPPKPSLCHRNSNGL	688



As can be seen in the alignment, Tang *et al.*, does not disclose, either expressly or inherently, a polypeptide *consisting* of SEQ ID NO: 13. Therefore, Tang *et al.* does not anticipate a polynucleotide encoding a polypeptide, wherein the polypeptide *consists* of the amino acid sequence of SEQ ID NO: 13. Nor does Tang *et al.* anticipate a polynucleotide *consisting* of SEQ ID NO: 56 (a polynucleotide sequence encoding SEQ ID NO: 13), or the complements of such polynucleotides. Likewise, vectors and cells transformed with such polynucleotides are also not anticipated.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

#### **VIII. Conclusion**

The present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: September 2, 2009

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